UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

KGV EASY LEASING CORPORATION, a corporation,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

Defendant.

CV 08-06281 DSF (RZx)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This matter came on for hearing on December 2, 2009, before the Honorable Dale S. Fischer, United States District Judge. The Court having considered the pleadings, memoranda of points and authorities, evidence, and the oral argument at the hearing, it is hereby ordered as follows:

FINDINGS OF FACT

A. Statutory and Regulatory Background

1. The Medicare Act, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg, pays for covered medical care provided to eligible aged and disabled persons. During the time at issue here, the statute consisted of three main parts.

2. Part B provides supplementary medical insurance for covered medical services, such as diagnostic testing, or covered medical supplies, such as durable medical equipment ("DME"), prosthetics and orthotics, 42 U.S.C. §§ 1395j to 1395w-4, 42 C.F.R. Part 410.

3. This case involves Part B of the Medicare Act because at all relevant times, Plaintiff KGV Easy Leasing Corporation ("KGV") was designated by Medicare as an Independent Diagnostic Testing Facility ("IDTF"). An IDTF is an entity independent of a hospital or physician's office in which diagnostic tests are performed by licensed, certified non-physician personnel under appropriate physician supervision. See 42 C.F.R. § 410.33(d). The sole purpose of IDTFs is to furnish tests; such entities do not directly use the test results to treat a beneficiary. 62 Fed. Reg. 59048, 59072 (October 31, 1997).

4. In administering Part B, the Centers for Medicare and Medicaid Services ("CMS") acts through private fiscal agents called carriers. 42 U.S.C. § 1395u; 42 C.F.R. Part 421, Subparts A and C, and 42 C.F.R. § 421.5(b). Carriers are private entities who contract with the Secretary and perform a variety of functions. These functions include making coverage determinations in accordance with the Medicare Act, applicable regulations, Medicare Part B Supplier Manual,

or other agency guidance; determining reimbursement rates and allowable payments; conducting audits of the claims submitted for payment; and rejecting or adjusting payment requests. On receipt of a claim for services rendered, the carrier pays the Medicare beneficiary on the basis of an itemized bill or pays the Medicare supplier on the basis of an assignment of benefits executed by the beneficiary. 42 U.S.C. § 1395u(b)(3)(B). These carrier functions are prescribed by regulation. 42 C.F.R. § 421.200.

5. As with private medical insurance programs, Medicare has conditions and limitations on the coverage of services and items. For Part B, the statute and implementing regulations set forth these conditions, exclude certain services and items from coverage, and otherwise specify various limitations. 42 U.S.C. §§ 1395k, 1395l, 1395x(s); see also 42 U.S.C. § 1395y(a)(1)-(16); 42 C.F.R. § 411.15(a)-(s).

6. For Medicare to cover an item or service, the services rendered must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C.§ 1395y.

7. Medicare payment cannot be made unless the party seeking payment furnishes the Secretary of the U.S. Department of Health and Human Services ("Secretary") with the information required to substantiate medical necessity. 42 U.S.C. § 1395l(e); 42 C.F.R. § 424.5(a)(6). Congress has given the Secretary the authority to prescribe the regulations for determining entitlement to benefits under part A or part B. 42 U.S.C. § 1395ff(a).

8. The medical documentation requirements that IDTFs must meet to be eligible for reimbursement for services to Medicare beneficiaries are published at 42 C.F.R. § 410.33.

9. The Medicare Act also provides for a waiver of liability for a supplier when the supplier "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services." 42 U.S.C. §

1395pp(a). The Act allows recovery by a supplier whenever it is determined that the supplier is "without fault" in incurring the denial of payment. 42 U.S.C. § 1395gg(b)(1).

10. A Medicare supplier dissatisfied with a reimbursement decision by the carrier must present its claim through the designated administrative appeals process and exhaust the administrative remedies available to it. 42 U.S.C. § 1395ff(b) (incorporating by reference 42 U.S.C. § 405(b)); see also, 42 C.F.R. § 405.801 et seq. (describing the administrative appeals process for Part B).

11. Once this administrative process is exhausted, judicial review of the Secretary's "final decision" is available as provided in 42 U.S.C. § 405(g) (incorporated by reference in 42 U.S.C. § 1395ff(b)(1)(A)).

B. Procedural History

12. At all times relevant herein, KGV was designated by Medicare as an IDTF.

13. KGV billed Medicare for providing IDTF services to Medicare beneficiaries between September 1, 2005 to February 28, 2006 (an additional claim for service on June 9, 2006 is also included). CAR at 4, 682-95; ACAR at 4, 560-73.[1] KGV submitted 386 claims.[2] ACAR at 560-73. Medicare's designated Part B fiscal contractor, the National Heritage Insurance Company ("NHIC" or carrier), denied KGV's claims initially and upon redetermination. See CAR at 4; ACAR at 4. KGV then submitted eight requests for administrative law judge ("ALJ") hearings, each with varying numbers of beneficiaries and claims. See CAR at 5; ACAR at 5.

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[1] The Certified Administrative Record is cited as "CAR" and followed by a citation to the relevant page number in the administrative record. For example, "CAR at 3" refers to page three of the Certified Administrative Record. The Abridged Certified Administrative Record is cited as "ACAR" and followed by a citation to the relevant page number.

[2] KGV submitted claims for 290 nerve conduction studies and 96 Doppler carotid studies. CAR at 14-19, 195; ACAR at 14-19, 195.

14. The ALJ consolidated the hearing requests into one proceeding. CAR at 375-80; ACAR at 283-89. Due to the large number of claims, the ALJ employed an independent statistician to create a statistically-valid random sampling of the claims. CAR at 392; ACAR at 301. That sample consisted of 15 claims. CAR at 402, 710-14; ACAR at 311, 586-90. KGV agreed by stipulation to the use of statistical sampling and did not dispute the hearing process, sampling methodology, or extrapolation. CAR at 357; ACAR at 265-66.

15. On January 31, 2008, the ALJ issued his decision, which concluded that KGV was not entitled to Medicare payment on the 15 sampled claims under review. CAR at 193; ACAR at 193. The ALJ found that KGV failed to produce the required documentation of medical necessity.[3] CAR at 212; ACAR at 212. From this determination, the ALJ extrapolated the results of the sample to the universe of claims, concluding that KGV was not entitled to reimbursement for any of the 386 claims. CAR at 217; ACAR at 217. The ALJ further held that because KGV knew or should have known of the documentation requirements, KGV did not qualify for payment under the waiver provisions of section 1879 of the Social Security Act ("the Act"), 42 U.S.C. § 1395pp. CAR at 216-17; ACAR at 216-17.

16. KGV sought review of the ALJ's decision by the MAC by a letter dated February 11, 2008. CAR at 41; ACAR at 41. On August 20, 2008, the MAC affirmed the ALJ's decision denying KGV reimbursement for the claims it submitted to Medicare. CAR at 11-12; ACAR at 11-13. The MAC decision constitutes the Secretary's final decision. Having exhausted its administrative remedies, KGV timely filed this action on September 24, 2008.

CONCLUSIONS OF LAW

[3] In eight of the fifteen sampled cases, the ALJ found that KGV had failed to submit any medical documentation, including the preprinted order forms, for the beneficiaries. CAR at 212-13; ACAR at 212-13. In its request for Medicare Appeals Council ("MAC") review, KGV attached the documentation. CAR at 3-4, 99-189; ACAR at 3-4, 99-189.

17. This is an action under 42 U.S.C. § 1395ff(b)(1)(a) for judicial review of a final decision by the Secretary.

18. Judicial review of the Secretary's final decision must be based solely on the record. The Secretary's final decision will be disturbed only if the factual findings underlying the decision are not supported by substantial evidence or if the decision fails to apply the correct legal standards. Tackett v. Apfel, 180 F.3d 1094, 1097 (9th Cir. 1999). The findings of the Secretary as to any fact shall be conclusive and must be upheld if supported by substantial evidence. 42 U.S.C. § 405(g); Mayes v. Massanari, 276 F.3d 453, 459 (9th Cir. 2001). Additionally, if the evidence can rationally be interpreted in more than one way, the court must uphold the Secretary's decision. Mayes, 276 F.3d at 459. Because an agency's action is presumed valid, the burden is on the party challenging the agency's action to show that it is arbitrary and capricious. Short Haul Survival Comm. v. United States, 572 F.2d 240, 244 (9th Cir. 1978).

19. Congress vested the Secretary with broad discretion to determine what information is required in order to establish medical necessity as a condition of payment. See Maximum Comfort, Inc. v. Sec'y of Health and Human Servs., 512 F.3d 1081, 1086-88 (9th Cir. 2007). The medical documentation requirements that IDTFs must meet to be eligible for reimbursement for services to Medicare beneficiaries are published at 42 C.F.R. § 410.33.

20. In support of its claim for payment, KGV submitted copies of its preprinted physician order forms. These forms, however, had numerous deficiencies and did not conform to the requirements of 42 C.F.R. § 410.33(d) for at least the following reasons:

a. 42 C.F.R. § 410.33(d) requires both that the tests be ordered by the beneficiary's treating physician and that the tests be used "in the management of the beneficiary's specific medical problem." Here, there is no indication on the preprinted order forms – or on any of the other documentation KGV submitted –

that either requirement was satisfied. See, e.g., CAR at 102, 112, 149, 483, 538; ACAR at 102, 112, 149, 361, 416 (order form from each of the five physicians in the sampled set of claims). The order forms KGV submitted in support of its claims for payment only identified the physician who referred the beneficiary for the test. See, e.g., CAR at 102, 112, 149, 483, 538; ACAR at 102, 112, 149, 361, 416 (order form from each physician in the sampled set of claims). None of the documentation KGV provided in support of its claims for payment establish that the referring physician named on the order form was the beneficiary's treating physician.

b. Further, there is no indication from the documentation KGV submitted that the tests were used "in the management of the beneficiary's specific medical problem." See, e.g., CAR at 99-108, 651-80; ACAR at 99-108, 529-58 (complete files for two sampled beneficiaries).

21. In addition to the requirements of 42 C.F.R. § 410.33(d), a Local Coverage Determination ("LCD")[4] issued by the carrier requires that the ordering physician clinically assess the patient and advises that "[s]ymptoms only are not adequate for presumptive diagnoses needing electrodiagnostic tests. It is the clinical picture and presumptive diagnoses that dictate the reasonableness and necessity of electrodiagnostic tests." CAR at 8; ACAR at 8 (quoting LCD L13569) (emphasis added). The LCD further states that "[d]ocumentation of the patient assessment prior to testing is expected." Id.(emphasis added).

22. KGV's claims did not conform to the requirements of LCD L13569 for at least the following reasons:

a. The only information regarding a beneficiary's clinical picture came from the preprinted order form from which a referring physician must select

[4] NHIC Local Coverage Determination ("LCD") L13569 provided KGV additional notice and guidance regarding the requirements necessary for reimbursement by Medicare for IDTF services. See CAR at 7-8; ACAR at 7-8.

preprinted symptoms and possible diagnoses.[5] CAR at 102, 112, 149, 483, 538; ACAR at 102, 112, 149, 361, 416. This did not conform to the requirements of LCD L13569 because it provided insufficient clinical information about the beneficiary.

b. Further, according to KGV, its standard procedure was to await a telephone call from a physician ordering a test and then set up a time for the KGV technician to go to the physician's office and conduct that test on the patient. KGV's Opening Brief at 13-14. In practice, however, the date of the physician order form is the same as the date of the services for each beneficiary considered by the ALJ and MAC. CAR at 213; ACAR at 213; see also CAR 102, 112, 149, 483, 538; ACAR at 102, 112, 149, 361, 416 (physician order form from each physician on which the date of the order and test are the same). Because the dates on the order forms and the dates the test were allegedly performed are the same, there is no indication that a relationship existed between the beneficiaries and ordering physicians prior to the ordering of the tests – as required by the LCD; and

c. KGV's preprinted physician order forms did not indicate that the dates shown on the orders are the actual dates the physician examined or consulted the patient. Id. Consequently, there is no indication that the beneficiary was assessed prior to the ordering of the test.

23. KGV knew at least by the time of the carrier's redeterminations that its preprinted forms did not meet the documentation requirements for reimbursement. See, e.g., CAR at 474; ACAR at 352 (redetermination decision). That message was reiterated in three more levels of administrative review,

[5] The beneficiaries' files also included the test results. However, the LCD in place at the time required there to be documentation of a patient's clinical picture and assessment before testing. CAR at 8; ACAR at 8.

including the MAC, ALJ, and QIC[6] decisions. CAR at 3, 190, 468; ACAR at 3, 190, 346. But KGV never addressed the problems cited by those reviews. KGV might have presented medical records, witness testimony, or submitted signed declarations from the various physicians named on the order forms attesting to the accuracy of the information allegedly contained on those forms. KGV chose to do none of those things.

24. KGV never presented medical records, witness testimony, or submitted signed declarations from the physicians named on the order forms attesting to the accuracy of the information allegedly contained on those forms, or submitted any other form of evidence that verifies the information allegedly contained on its order forms or establishes medical necessity.

25. Nor has KGV presented any other form of evidence that verifies the accuracy of the information contained on its order forms or establishes medical necessity. In fact, during the hearing held before the ALJ, KGV chose not to submit any additional evidence or put forth any witnesses. CAR at 14398-14398-9, 14407-10; ACAR at 643-4, 652-55. Instead, KGV simply introduced its preprinted order as exhibits to attempt to establish the medical necessity of the tests it allegedly performed. Id.

26. The ALJ and MAC reasonably concluded that KGV failed to meet the medical documentation requirements that IDTFs must meet to be eligible for

[6] QIC stands for "Qualified Independent Contractor." 42 C.F.R. § 405.902. It is an entity that contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978. Id. The QIC responsible for independently reviewing KGV's claims in this case was Q^2 Administrators, LLC. See CAR 468; ACAR at 346 (letter from Q^2 administrators to KGV denying claim for test allegedly performed on Medicare beneficiary). The QIC panel that reviewed KGV's documentation was composed of board-certified physicians and licensed registered nurses. ACAR at 347.

reimbursement for services to Medicare beneficiaries. See 42 C.F.R. § 410.33.[7]

27. If services are not medically necessary, Medicare payment may still be made pursuant to a "waiver" provision contained in section 1879 of the Social Security Act, 42 U.S.C. § 1395pp. Medicare payment may be made if "neither the beneficiary or the provider knew or reasonably could have been expected to know that such services would be excluded from Medicare coverage." 42 U.S.C. § 1395pp(a).

28. As a Medicare supplier, KGV was charged both with knowledge of those regulations and with the understanding that Medicare would not provide reimbursement for services that are not demonstrably medically necessary and otherwise properly documented. See, e.g., Federal Crop Ins. Corp. v. Merrill, 332 U.S. 380, 384 (1947) (the appearance of rules and regulations in the Federal Register gives legal notice of their contents); Maximum Comfort, 512 F.3d at 1088 (supplier charged with constructive notice of publications from the Medicare contractor setting forth documentation requirements for suppliers of durable medical equipment).

29. In this case, the medical documentation requirements for IDTFs are contained in federal regulations that took effect on January 1, 1998, i.e., over seven years before the earliest of the claims in question here. See 62 Fed. Reg. 59048 (October 31, 1997). Therefore, KGV is not entitled to a waiver under section 1879 of the Social Security Act, 42 U.S.C. § 1395pp.

CONCLUSION

For the foregoing reasons, the Secretary's final decision in this matter is without legal error and is supported by substantial evidence. Therefore, it is

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[7] KGV argues that it was prohibited by the Privacy Act from obtaining copies of beneficiaries' medical records. However, KGV's argument is without merit because the Privacy Act applies only to records kept by agencies of the federal government, not private physicians. 5 U.S.C. § 552a(a)(1); 5 U.S.C. § 552(e) (defining "agency").

sustained by this Court.

DATE: 1/29/10

DALE S. FISCHER
UNITED STATES DISTRICT JUDGE